Senior Manager, Regulatory Compliance and Professional Services

AREAS OF EXPERTISE

- **Audits and Gap Analysis: FDA 21 CFR parts 11, 210/211, 820, 600, QSIT, GXP, ISO 9001/13485/14971/17025/10993/14644/ 60812, etc.**
- **Quality Systems and Management Controls: Development of Quality Programs, SOP/Work Instructions, Quality Manual, Document Controls, Manufacturing, Batch Record Review, Deviations / nonconformance / Corrective and Preventive Actions, Customer Complaints, Medical Device Reporting, Field Alerts, Adverse Event Evaluation and FDA Reporting, Recall Management, Change control, Trending/Analysis and Training**
- **Production Controls: Process Validation / Consistency of lots, Aseptic Processing, Media Runs, Clean Rooms Qualification, Environmental Monitoring, Failure Investigations, Sterilization, Cleaning Validation and Process Engineering support**
- **Packaging & Labeling Controls: Container closure and integrity studies, shipping validations and product packaging and labeling**
- **Pre-approval Inspection (PAI): FDA inspection support, resolving FDA 483's and Warning Letters and Response to Regulatory Observations.**
- **Facilities and Equipment Controls: Review of Facility and Equipment Qualifications (DQ, IQ, OQ, PQ), Software Validation Reports, Equipment Qualifications, Calibration / Preventive Maintenance documentation.**
- **Materials Controls: Development / implementation and Management of Supplier Qualification Programs, Quality / Technical Agreements, incoming materials receipt/storage, sampling and testing; nonconforming materials.**
- **Laboratory Controls: Chemistry, Microbiology, Out-of-Specification (OOS) Investigations, Equipment / Instrument Controls, Contamination Control and Environmental Monitoring, Stability Programs, Sterility, Method Validation and Method transfer, sample receipt/storage and handling, retain samples**
- **Submissions Review: 510(k), PMA, CMC, DMF, BLA, Combination Products, ELA, PLA, IDE, IND, NDA, ANDA**

INTRODUCTION

Professional with more than 30 years of experience, knowledge and understanding of the regulatory framework of healthcare laws and regulatory compliance to the Medical Device, Pharmaceutical, Biotechnology and Dietary Supplement industries, specializing in Quality/Regulatory cGMP, GCP and GLPs as well as ICH and ISO compliance. Expertise with Food and Drug Administration regulations, Medical Device Directive (MDD), EU, Medicines Control Agency, Health Canada (HPFBI), Mexican Health Authority, and ISO Standards and can provide technical support during these inspections and audits.

WORK EXPERIENCE

2000 – Present
Industry Consultant
Duties:
As a Senior Quality Systems Consultant, work with clients in the *pharmaceutical, medical device, biologics, and biotechnology* industries to develop quality assurance and regulatory strategies for compliance with FDA regulations.

- Conducting gap assessments of client systems, studies, procedures, and programs to determine regulatory compliance. Develop and implement corrective action plans/Quality Enhancement Programs to address deficiencies
- Conducting pre-approval preparations for FDA inspections and corrective action implementations after the inspections
- Developing and implementing quality systems policies, procedures and programs that meet regulatory requirements (both in English and Spanish) and ISO Standards, when appropriate. Development of Risk Management Programs, Design Controls, Document Controls, Purchasing controls, Identification/Traceability, Production and Process Controls, Acceptance Activities, Nonconforming Products, Corrective and Preventive Action, Labeling and Packaging, Handling/Storage/Distribution/Installation, Records, Servicing and Statistical Techniques, CAPA, Change Controls, Material Controls, Supplier Management, Internal Audits and Training.
- Developing programs and managing Customer Complaints, MDRs and Product Field Actions and performing evaluations of complaints to determine reportability as per 21 CFR. Reporting complaints to FDA authorities, as needed. Interfacing with all divisions domestically and internationally ensuring the systems developed met the requirements of US, Europe, Canada and Asia**.**
- Managing Training Programs; developing personnel Job Descriptions/Training Curricula and presenting GMP/QSR training (both in English and Spanish).
- Performing investigations of deviations, nonconforming products, *customer complaints*, OOS and OOTs. Developing CAPA strategies.
- Implementing vendor audit programs, quality agreements and performing vendor audits including API, component manufacturers and laboratory services
- Developing and publishing Product Annual Reports.
- Project Planning and follow up
- **Medical Device** related projects have included manufacturers under Warning Letters or Consent Decree;
    - One (2) manufacturer of infusion medical devices and needle-free IV sets and accessories.
    - Two (2) manufacturers of orthopedic implantable and thoracolumbar medical devices for the spine, knees and hips; Class I, II and III (U.S.) Implants and Surgical Instruments.
    - One (1) manufacturer of Iontophoresis / transdermal drug delivery devices
    - One (1) manufacturer of implantable dental medical devices
    - Two (3) separate projects for manufacturers of Carotid Artery Stent and Monorail Delivery Systems
- **Pharmaceuticals** related projects have included the establishment of Quality Programs in defined systems Quality Systems, Materials Controls, Facilities/Equipment, Production, Packaging/Labeling, Laboratory; preparation and implementation of QA/QC documentation, policies, and procedures, Master Batch Record preparation and new standard operating procedure (SOP) preparation, Batch Record data review and approval, routine GMP compliance, including establishment of Vendor Audit Programs, Internal Audit Programs. Conducted, managed and supervised internal investigations, fact finding and remediation strategies to detect and resolve compliance issues relating to clinical research and commercial product including customer complaint investigations and evaluations, and FDA AE reporting. Providing CGMPs Training including Adverse Event and Field Alert Reporting and

supporting in the supplier qualification programs; Audits have included CROs utilized for performing clinical studies as well as clinical materials manufacturers, API vendors, Laboratories, Sterilization services, and contract manufacturers as well as foreign companies to determine QS implementation based on FDA regulations. Long term projects have included manufacturers under Warning Letters or Consent Decree;

- 5 manufacturers of injectable drugs
- 1 manufacturer of prescription tablets

03/1996 – 11/1999
GensiaSicor Pharmaceuticals, Irvine, CA
(Currently TEVA, USA)
Senior Manager, Regulatory Compliance and Professional Services/Customer Compliance
Duties:

- Managing the company's compliance program to FDA regulations, foreign regulatory agencies, such as the EU British Medicines Control Agency and the Mexican Health Authorities, and responding to regulatory agencies observations. As a result; coordinated, managed, and participated in six (6) FDA pre-approval inspection for an NDA submission.
- Initiating and implementing corporate policies and business conduct practices for the aseptic processing manufacturer to ensure general corporate compliance for drug delivery systems and combination (drug/device) products for human use including; the internal Audit Program and the Supplier Audit Programs, Negotiating and structuring supplier and distribution Quality Agreements, Managing a team of Auditors and department Administrative Assistant.
- Developing and managing the department budget
- Hiring, oversight of qualified personnel and performing annual employee performance reviews
- Assisting in companywide GMP Training and Pre-approval inspection (PAI) training

10/2003 – 2005
Yamanouchi Pharmaceuticals, Inc., Oklahoma and Yaizu, Japan
Consultant
Duties:
PAI Gap Assessment for an aseptic processing drug manufacturer located in Japan in preparation for an NDA submission. Audited the newly constructed manufacturing facilities in Ohio to determine compliance to FDA requirements and commissioning requirements.

01/2002 – 2003
Nutri Granulations, La Mirada, CA
Consultant
Duties:
Technical Advisor and Quality Systems, development of QS procedures, VMP, equipment qualifications and personnel training with the intent of upgrading the systems in compliance to cGMPs for pharmaceutical manufacturers (API/excipient)

01/2002 – 09/2004
Lee Pharmaceuticals, Inc., El Monte, CA
QA/RA Technical Advisor for OTC manufacturer
Duties:
Developed Quality Systems and personnel training as a corrective action response to an inspection by the So. California FDA. Prepared monthly reports to FDA headquarters.

09/2001 – 2008
Prism Pharmaceuticals, Brea, CA
As needed – RA/QA Technical Advisor to OTC manufacturer

EDUCATION

- School of Medicine and Dentistry of NJ; Newark, NJ
  Graduate Studies in Medical Technology (Medical Technology Certified)

- Fairleigh Dickinson University, Rutherford, NJ
  Graduate Studies in Biological Sciences

- New Jersey City State College, Jersey City, NJ
  Bachelor of Science in Biology and Chemistry
  Minor in Spanish

ADDITIONAL TRAINING HAS INCLUDED BUT IS NOT LIMITED TO

Orange County Regulatory Affairs Certification Program
Laboratory Applications of GMPs
The Quality Auditor Primer
How to Effectively Prevent a Warning Letter
Methods Development and Validation: FDA Requirements in Analytical Chemistry
OOS Investigation Reporting
Equipment Cleaning Validations

LANGUAGES

English
Spanish (speak, read and write). Gap Assessment